DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 7, 2015

K2M, Incorporated
Ms. Nancy Giezen
Manager, Regulatory Affairs
571 Miller Drive Southeast
Leesburg, Virginia 20175

Re: K142487
Trade/Device Name: Chesapeake Stabilization System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, OVE
Dated: April 21, 2015
Received: April 22, 2015

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142487

Device Name
Chesapeake Stabilization System

Indications for Use *(Describe)*
When used as a cervical intervertebral body fusion device, the CHESAPEAKE Stabilization System implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.
When used as a lumbar intervertebral body fusion device, the CHESAPEAKE Stabilization System implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The Lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.
The hyperlordotic lumbar implants (i.e., > 15°) must be used with supplemental fixation (i.e., posterior pedicle screw and rod system) cleared for use in the lumbar spine, in addition to the bone screws provided. Otherwise, the Chesapeake Stabilization System implants (i.e., ≤ 15°) may be used as a stand-alone device, which is intended to be used with the bone screws provided (i.e., 2 or 3 screws for the 2-screw and 3-screw implants, respectively).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Chesapeake Stabilization System
K2M, Inc.

Submitter

K2M, Inc.
751 Miller Drive SE
Leesburg, VA 20175

Contact Person: Nancy Giezen
Telephone: 703-777-3155
Date Prepared: 05/05/2015

Classification

Trade Name: Chesapeake Stabilization System
Common Name: Spinal Fixation System
Regulatory Class: Class II

Classification Name(s):
Intervertebral Body Fusion Device with Integrated Fixation (21 CFR 888.3080, Product Code OVD, OVE)

Predicate Device(s)

Primary Predicate:
K2M Chesapeake (K092211)
Additional Predicates:
K2M Chesapeake (K111439, K133494)
K2M Aleutian (K082698, K133614)
NuVasive Brigade (K123045)

Device Description

The spacers are manufactured from Medical Grade PEEK (Polyetheretherketone) OPTIMA® LT1 (Invibio™) per ISO 10993-1 USP Class VI, and ASTM F2026 and CP titanium per ASTM F67. Tantalum beads /rods to be Grade UNS R05200, UNS R05400 according to ASTM F560. The screws are fabricated from Ti6Al4V per ASTM 1472.

Function: The system functions as an intervertebral body fusion device to provide support and stabilization of the cervical and lumbar segments of the spine.

The purpose of this 510(k) submission is primarily to add additional cervical and lumbar lordotic implants.

Intended Use

When used as a cervical intervertebral body fusion device, the CHESAPEAKE Stabilization System implants are indicated for spinal fusion procedures to be used with autogenous bone graft

in skeletally mature patients. Cervical IBF implants are intended for use at one level in the cervical spine, from C2 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is intended to be used in patients who have had six weeks of non-operative treatment.

When used as a lumbar intervertebral body fusion device, the CHESAPEAKE Stabilization System implants are indicated for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients. The Lumbar IBF implants are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is intended to be used in patients who have had six months of non-operative treatment.

The hyperlordotic lumbar implants (i.e., > 15°) must be used with supplemental fixation (i.e., posterior pedicle screw and rod system) cleared for use in the lumbar spine, in addition to the bone screws provided. Otherwise, the Chesapeake Stabilization System implants (i.e., ≤ 15°) may be used as a stand-alone device, which is intended to be used with the bone screws provided (i.e., 2 or 3 screws for the 2-screw and 3-screw implants, respectively).

Technological Comparison to Predicate(s)

The Chesapeake Stabilization System was compared to predicate systems and were found to be substantially the same as these systems.

Non-clinical Performance Evaluation

Mechanical testing including static compression, static torsion, static compression shear, dynamic compression and dynamic torsion (per ASTM F2077), expulsion, and subsidence (per ASTM F2267) was performed in support of this submission and the proposed implants were determined to be substantially equivalent to predicate devices.

Conclusion

There are no significant differences between the proposed Chesapeake spacers and other devices currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.